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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,170	02/22/2002	Yoshihiro Kawaoka	800.029US1	8446

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/081,170

Applicant(s)

KAWAOKA, YOSHIHIRO

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 16-35 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) 12-14 and 16-31 ~~is/are~~ are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 32-35 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO APPLICANTS' AMENDMENT

Applicant's Amendment

- 1) Acknowledgment is made of Applicant's amendment filed 04/15/04 in response to the non-final Office Action mailed 01/15/04. With this, Applicant has amended the specification.

Status of Claims

- 2) Claim 15 has been canceled via the amendment filed 04/15/04.
Claims 1, 4 and 12 have been amended via the amendment filed 04/15/04.
New claims 32-35 have been added via the amendment filed 04/15/04.
Claims 1-14 and 16-35 are pending.
Claims 1-11 and 32-35 are under examination.

Prior Citation of Title 35 Sections

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

- 5) The objection to the drawings made in paragraph 6 of the Office Action mailed 01/15/04 is withdrawn in light of Applicant's amendments.
6) The objection to the specification made in paragraph 8 of the Office Action mailed 01/15/04 is withdrawn in light of Applicant's amendments to the specification.
7) The objection to claim 1 made in paragraph 14 of the Office Action mailed 01/15/04 is withdrawn in light of Applicant's amendment to the claim.

Rejection(s) Withdrawn

- 8) The rejection of claim 4 made in paragraph 10(a) of the Office Action mailed 01/15/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim
9) The rejection of claim 1 made in paragraph 10(b) of the Office Action mailed 01/15/04 under

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35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim

10) The rejection of claims 2-11 made in paragraph 10(c) of the Office Action mailed 01/15/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the base claim.

11) The rejection of claims 2, 3 and 5-11 made in paragraph 11 of the Office Action mailed 01/15/04 under 35 U.S.C. § 112, first paragraph, as containing inadequate written description, is withdrawn upon further consideration.

Rejection(s) Maintained

12) The rejection of claim 1 made in paragraph 11 of the Office Action mailed 01/15/04 under 35 U.S.C. § 112, first paragraph, as containing inadequate written description, is maintained for reasons set forth therein and herebelow.

Applicant cites a part of *Written Description Requirement Guidelines* and contends that to provide an adequate written description for a claimed genus, the specification can provide a sufficient description of a representative number of species by an actual reduction to practice, reduction to drawings, or by a disclosure of relevant identifying characteristics. Applicant submits a chapter from *Fields Virology*, which lists cells from organisms recognized as being susceptible to influenza virus infection, e.g., bovine cells, swine cells, ferret cells, human cells, canine cells and avian cells.

Applicant asserts that the specification has disclosed relevant identifying characteristics of the claimed genus of mutant cells by disclosing a functional characteristic coupled with a known or disclosed correlation between function and structure, e.g., the use of lectins which binds sialic acid to select for cells with reduced sialic acid-containing molecules that are receptors for influenza virus. Applicant concludes that one skilled in the art would recognize that Applicant was in possession of the necessary common attributes or features of the elements possessed by members of the genus.

Applicant's arguments have been carefully considered, but are non-persuasive with regard to what is claimed in claim 1. The mutant cell genus claimed in claim 1, includes within its scope, non-mammalian mutant cell species. Applicant's own acknowledgment of the description of bovine cells, swine cells, ferret cells, human cells, canine cells and avian cells as supported by the disclosure of the submitted chapter from *Fields Virology* provides the *prima facie* evidence that the written

description provided within the instant specification is limited to mammalian cells having the recited characteristics. As set forth previously, adequate written description requires more than a mere statement that its is a part of the invention and a reference to a potential method of isolating it. The non-mammalian mutant cell having the recited structural and functional properties itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. The rejection stands.

13) The rejection of claims 1-4 and 8 made in paragraph 13 of the Office Action mailed 01/15/04 under 35 U.S.C. § 102(b) as being anticipated by Martin *et al.* (*Virology* 241: 101-111, 1998) or Brandli *et al.* (*J. Biol. Chem.* 263: 16283-16290, 1988), is maintained for reasons set forth therein and herebelow.

Applicant acknowledges that Martin's ricin-resistant MDCK mutant cell was greatly reduced in infectivity by influenza viruses compared to wild-type MDCK cells. Applicant also acknowledges that Martin disclosed a 70 to 75% reduction in cell surface sialic acid in the ricin-resistant MDCK cells.

With regard to the teachings of Brandli *et al.*, Applicant states that Brandli's ricin-resistant MDCKII cells bind wheat germ agglutinin specific for N-acetylneuraminic acid and N-acetylglucosamine. Applicant acknowledges that mutant cells had 70 to 75% decreased binding to *Limax flavus* agglutinin, a lectin which binds sialyl residues. Applicant describes of the binding of Brandli's ricin-resistant MDCK cells to lectins that are not specific for N-acetylneuraminic acid. Applicant submits a post-filing 2003 reference of Cross *et al.* Applicant concludes that Brandli's ricin-resistant MDCKII cells are deficient in the addition of galactose residues to – and O-linked glycans. Applicant alleges that none of the cited references discloses a cell line which has reduced levels of terminal sialic acid, e.g., reduced levels of N-acetylneuraminic acid.

Applicant's arguments have been carefully considered, but are non-persuasive. Claim 1, for example, is directed to any mutant cell comprising decreased levels of sialic acid-containing host cell receptors for influenza virus relative to a corresponding wild-type cell. The new limitation 'selected for ...' is a process limitation in a product claim. The claim(s) does not include the recitation of any 'terminal' sialic acid. As Applicant acknowledges, the prior art mutant MDCK cells have a 70 to 75% reduction in cell surface sialic acid and a capacity to produce reduced influenza virus yields and

therefore, anticipate the claimed invention. Applicant's discussion of the alleged binding of Brandli's ricin-resistant MDCK cells to lectins that are not specific for N-acetylneuraminic acid is not relevant. The rejection stands.

New Rejection(s)

Applicant is asked to note the following new rejection(s) made in this Office. The new rejections are necessitated by Applicant's amendments, i.e., the submission of new claims.

Rejection(s) under 35 U.S.C § 112, First Paragraph (New Matter)

14) Claim 1 and those dependent therefrom are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The newly added limitation 'sialic acid-containing molecules' in claim 1 is new matter. Applicant points to originally filed claims 1 and 12 as providing support for the new limitation. However, claim 12, for example, recited a lectin that specifically binds 'sialic acid', but not 'sialic acid-containing molecules'. The two limitations are not of same scope. Therefore, the limitation in the claims is considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicant is respectfully requested to remove the new matter from the claim(s), or to point to specific pages and line numbers in the originally filed specification where support for such a recitation can be found.

15) Claim 33 and those dependent therefrom are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

New claim 33 includes the limitations: 'mutant cell of claim 1 in which influenza virus with reduced sialidase activity efficiently replicate'. Applicant states that the new claim 33 is supported by the example of the specification. However, there appears to be no descriptive support for the above-

identified phrase. Therefore, the limitations in the claim are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicant is respectfully requested to remove the new matter from the claim(s), or to point to specific pages and line numbers in the originally filed specification where support for such a recitation can be found.

Rejection(s) under 35 U.S.C § 112, Second Paragraph

16) Claims 33 and 35 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 33 is grammatically incorrect in the recitation: 'influenza virus replicate'. It is suggested that Applicant replace the limitation with --influenza virus replicates--.

(b) Analogous criticism applies to claim 35 with regard to the recitation: 'lectin ... bind'. It is suggested that Applicant replace the limitation with --lectin binds--.

Remarks

17) Claims 1-11 and 32-35 stand rejected.

18) Applicant's amendments necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

19) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center which receives transmissions 24

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hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

20) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

21) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system. A message may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

July, 2004


S. DEVI, PH.D.
PRIMARY EXAMINER